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Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Lonnie Witham
Telephone: (219) 267-6639
Fax: (219) 372-1683

Proprietary Name: Titanium Retrograde Femoral Nail – 13 MM Diameter

Common Name: Titanium Intramedullary Nail (Rod)

Classification Name: Intramedullary Rods (21 CFR 888.3020)

Legally Marketed Devices to Which Substantial Equivalence Is Claimed:
These devices are substantially equivalent to Biomet Titanium Intramedullary Nails previously cleared in K982953.

Device Description: Intramedullary rods made of titanium alloy are used for the same indications as stainless steel intramedullary rods that have been commercially available continually since the 1950s. These devices are to be implanted by insertion into the long bones for fixation of fractures, or the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity, or arthrodesis. Transverse screws can be used to further stabilize bone fragments distally and proximally, as needed. A wide variety of titanium intramedullary nails indicated for used in long bones (femur, tibia, fibula, humerus, radius, and ulna were cleared for commercial distribution in Biomet 510(k) premarket notification (K982953).

These 13 mm diameter nails have the same intended use, warnings and precautions as those nails previously cleared in K982953. A new 13 mm size is being added in 20cm, 24cm, 28cm, 32cm, 34cm, 36cm, 38cm, 40cm and 44cm lengths to expand the product line. The 13 mm diameter is larger than the retrograde style nails previously cleared.

Intended Use: The Titanium Retrograde Femoral Nail is indicated for internal fixation and stabilization of the femur. These devices are implanted by insertion into the medullary canal of the femur for fixation of open and closed acute distal femoral fractures, pathological fractures, malunions, nonunions, failed plate/screw osteosyntheses of the distal femur, fractures proximal to a total knee arthroplasty, fractures distal to a total hip prosthesis, and fixation of a surgically prepared femur (osteotomy) for correction of deformity.

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Summary of Technology: This device utilizes standard technology that is commonly known by physicians. This technology has been used in commercially available metallic internal fixation devices prior to May 28, 1976. This particular device is a tubular metal rod that is inserted into the medullary canal of the femur to stabilize bone fragments until healing has occurred.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lonnie Witham
Biomet Orthopedics, Inc.
P. O. Box 587
Warsaw, Indiana 46581

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Re: K013923
Trade/Device Name: Titanium Retrograde Femoral Nail - 13mm Diameter
Regulation Number: 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: November 21, 2001
Received: November 27, 2001

Dear Mr. Witham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Millerman

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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STATEMENT OF INDICATIONS FOR USE

510(k) Number_____

Device Name: Titanium Retrograde Femoral Nail – 13mm Diameter

Indications for Use:

Femoral nails are to be used for treatment of fractures of the femur including: non-comminuted and comminuted mid-shaft fracture, subtrochanteric fracture, distal third fracture, combination fractures of the head and femoral neck, intertrochanteric fracture, combination intertrochanteric and subtrochanteric fractures. Other indications include: osteotomy and reconstructive procedures following tumor resection, and revision procedures where other treatments or devices have failed.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013923